

Thomas R. Cech et al.  
Application No.: 08/912,951  
Page 3

PATENT

SEQ ID NO:1 did not appear in claims 83-90 as previously presented. Accordingly, coverage is maintained for all equivalents of SEQ ID NO:1 in the claimed subject matter for which applicants were previously entitled.

Rejection Under 35 USC § 112:

Claims 83-90 stand rejected under 35 USC § 112 ¶ 1 on the basis that SEQ ID NO:224 contains only 20 nucleotides, and is not described in the application as an essential or distinguishing feature of a functional telomerase reverse transcriptase (hTRT). Claims 83-90 stand rejected under 35 USC § 112 ¶ 1 on the basis that the sequence is not enabled for SEQ ID NO:224 as an essential or distinguishing feature of hTRT.

By way of this amendment, reference to SEQ ID NO:224 is deleted, and replaced with SEQ ID NO:1. The encoding sequence for hTRT is SEQ ID NO:224 in priority application 08/854,050, but SEQ ID NO:1 in the present disclosure. It will be clear from the prosecution of this application that applicants intended this patent to protect embodiments related to SEQ ID NO:1. Applicants are grateful to the Examiner for discovering this clerical error.

The amendment to claim 83 renders these rejections moot. Withdrawal of the rejections is respectfully requested.

Applicants respectfully submit that the claims as amended comply with both the written description requirements and enablement requirements of 35 USC § 112 ¶ 1 in reference to SEQ ID NO:1.

The application meets the description requirements by indicating that SEQ ID NO:1 is the TRT sequence determined from a cloned TRT cDNA isolated from human cells, and by defining and using stringent hybridization conditions. One skilled in the art would recognize that applicants had possession of the invention as required by the standard set forth in *Regents of University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). SEQ ID NO:1 is representative of the genus of functional TRT encoding sequences, as referred to in the claims. In the *Written Description Training Examples* used in the Office, Example 9 indicates that

Thomas R. Cech et al.  
Application No.: 08/912,951  
Page 4

PATENT

claims reciting stringent hybridization conditions and functional activity meet the written description requirements of 35 USC § 112 ¶ 1.

The Office Action acknowledges that the specification is enabling for a polynucleotide with the sequence of SEQ ID NO:1 (page 4 of the Action). The only remaining question is whether homologs of TRT encoded by polynucleotides that hybridize under stringent conditions to a sequence complementary to SEQ ID NO:1 are also enabled.

The Office Action indicates that it is not routine to screen large numbers of nucleic acids that might potentially encode functional protein, where the expectation of obtaining similar activity is unpredictable.

With due respect, applicants submit that this is not the standard for the enablement requirement of 35 USC § 112 ¶ 1. The Federal Circuit has decided that the PTO should not reject generic claims where those skilled in the art using knowledge in the art and applicant's written disclosure could produce other species falling within the generic class without undue experimentation. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Techniques need not be foolproof: a lack of certainty and the need for repetition does not indicate that undue experimentation is required. The test for undue experimentation is not merely quantitative. A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides reasonable guidance. *Johns Hopkins University v. Cellpro, Inc.*, 47 USPQ2d 1705 (Fed. Cir. 1998), referring to *PPG Industries, Inc., v. Guardian Industries Corp.*, 37 USPQ2d 1618 (Fed. Cir. 1996).

The specification provides a number of assays for determining telomerase activity, as recited in the claim. See, for example, pages 40-45. One skilled in the art may readily make functional variants of SEQ ID NO:1 without undue experimentation by introducing mutations by standard techniques, and then testing the mutants for telomerase activity according to an assay taught in the specification. In a similar fashion, one having possession of a particular polynucleotide may determine whether it falls within the scope of the claim by testing it for hybridization to SEQ ID NO:1 under stringent conditions, and then conducting a telomerase

Thomas R. Cech et al.  
Application No.: 08/912,951  
Page 5

PATENT

assay on the encoded protein to determine whether it has the required functional activity. Accordingly, the scope of the claimed invention is enabled by the specification.

The Office acknowledged that polynucleotides that hybridize under stringent conditions to SEQ ID NO:1 are both described and enabled in the specification of priority application 08/854,050 — since this application issued as U.S. Patent 6,261,836 on July 17, 2001. The disclosure of 08/854,050 is incorporated by reference into the disclosure of the present application, which in addition provides further illustrations of the features of TRT and its use.

Accordingly, the application complies with the patentability requirements of 35 USC § 112 ¶ 1 for the claimed subject matter.

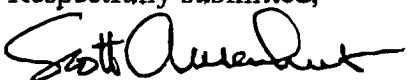
Conclusion

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and an early Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicants hereby request an interview by telephone.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief. The Assistant Commissioner is hereby authorized to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 20-1430.

Respectfully submitted,



Scott L. Ausenhus  
Reg. No. 42,271

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: (415) 576-0200  
Fax: (415) 576-0300  
SLA:mcl  
DE 7063228 v1

Thomas R. Cech et al.  
Application No.: 08/912,951  
Page 6

PATENT

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Specification:**

The title of this Application has been amended as follows:

**HUMAN TELOMERASE CATALYTIC SUBUNIT:  
DIAGNOSTIC AND THERAPEUTIC METHODS**

**TELOMERIZED MAMMALIAN CELLS**

**In the Claims:**

Claim 83 has been amended as follows:

83. *(Amended)* A mammalian cell that contains a recombinant polynucleotide comprising a nucleic acid sequence that encodes a ~~human~~ telomerase reverse transcriptase (~~hTERT~~) protein, variant, or fragment having telomerase catalytic activity when complexed with a telomerase RNA, wherein said recombinant polynucleotide hybridizes under stringent conditions to a polynucleotide having a sequence complementary to ~~SEQ. ID NO:224~~ SEQ ID NO:1.

84. The mammalian cell of claim 83, wherein the recombinant polynucleotide encodes a full-length naturally occurring ~~human~~ telomerase reverse transcriptase.

85. The mammalian cell of claim 83, which expresses said encoding sequence at the mRNA level, as measured by PCR amplification.

86. The mammalian cell of claim 83, which expresses said encoding sequence at the protein level, as measured by immunoassay.

87. The mammalian cell of claim 83, which has telomerase activity, as measured in a primer elongation assay.

88. The mammalian cell of claim 83, which is a human cell.

89. The mammalian cell of claim 83, which is a stem cell.

90. The mammalian cell of claim 88, which is a stem cell.

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.